PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 6,936,416	)	Serial No. 09/950,024
	)	
Inventor(s): Hua ZHU *et al*	)	Filed: September 12, 2001
	)	
Issue Date: August 30, 2005	)	Attorney Docket No. 003848.00096

For: EXPRESSION MONITORING FOR HUMAN CYTOMEGALOVIRUS (HCMV) INFECTION

REQUEST FOR CERTIFICATE OF CORRECTION

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building, Mail Stop: Certificate of Correction Branch
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 35 U.S.C. § 254 and 37 C.F.R. § 1.322, this is a request for the issuance of a Certificate of Correction in the above-identified patent. Two (2) copies of PTO Form 1050 are appended. The complete Certificate of Correction involves one page.

The mistakes identified in the appended Form occurred through no fault of the Applicants, as clearly disclosed by the records of the application, which matured into this patent. Enclosed for your convenience are the relevant portions of the Amendment filed January 18, 2005 and the Information Disclosure Statement initialed and returned with the Office Action dated January 14, 2004.

Issuance of the Certificate of Correction containing the corrections is respectfully requested. Since these changes are necessitated through no fault of the Applicants, no fee is believed to be associated with this request. Nonetheless, should the Patent and Trademark Office determine that a fee is required, please charge our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: March 13, 2006

By: _____
Sarah A. Kagan
Registration No. 32,141

1001 G Street, N.W. (11th Fl.)
Washington, D.C. 20001
(202) 824-3000

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 6,936,416

DATED: August 30, 2005

INVENTOR(S): Hua ZHU *et al*

It is certified that an errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Page 2 of the cover page, References Cited section (56), Other publications:
In the last reference of the second column:
Please replace "Apr. 1996" with --Apr. 1998--

In Column 37, Claim 1, Line 30:
Please replace "X5949," with --X15949,--

In Column 37, Claim 2, Line 67:
Please replace "(JRF-1);" with --(IRF-1);--

In Column 38, Claim 2, Line 37:
Please replace "est U78027" with --est=U78027--

In Column 38, Claim 3, Line 65:
Please replace "kDaI15" with --kDa/15--

In Column 38, Claim 3, Line 67:
Please replace "in doleamine" with --indoleamine--

Mailing Address of Sender:

Banner & Witcoff, Ltd.
11th Floor
1001 G Street, N.W.
Washington, DC 20001-4597

FORM PTO 1050 (Rev.2-93)

U.S. PAT. NO 6,936,416

No. of add'l copies
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U.S. PAT. NO 6,936,416

No. of add'l copies
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☐

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No. 1919
Hua ZHU	)	Group Art Unit: 1637
Serial No. 09/950,024	)	Examiner: Y. Kim
Filed: September 12, 2001	)	
For: **Expression Monitoring for Human Cytomegalovirus (HCMV) Infection**	)	Atty. Docket No. 003848.00096

AMENDMENT UNDER 37 C.F.R. 1.116

Commissioner of Patents
c/o Customer Service Window, Box AF
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In response to the final Office Action mailed July 28, 2004, and the advisory action mailed September 2, 2004, applicants request entry of the following amendments. The amendments to claims 1-3, 5-15, and 30-36 were requested in the Amendment filed August 24, 2004, but were not entered due to other amendments requested for claims 18-23. Claims 18-23 are cancelled in this paper. It is respectfully submitted that the remaining claims are now in condition for allowance based on the currently requested amendments.

A petition for extension of time for 3 months accompanies this paper. It is believed that no other fee is due at this time. However, the Commissioner is authorized to charge our Deposit Account 19-0733 should it determine any additional fee is required.

Status of the Claims:

Claims 1-3, 5-16, and 30-43 are pending.

Claims 4, 17-29, and 44-47 are cancelled.

Claims 1-3, 5-15, and 30-36 are amended herein.

Amendments to the Claims are reflected in the Listing of Claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

IN THE CLAIMS:

1. (Currently amended) A method of determining the stage of disease caused by HCMV infection, comprising the step of:

determining expression levels in a first human cell sample of a set of genes comprising M24594, Interferon stimulated genes 54K; M87434, 71 kDa 2'5' oligoadenylate synthetase; X02875, (2'-5') oligo A synthetase E (1.8 kb RNA); X02874, (2'-5') oligo A synthetase E (1.6 kb RNA); M87284, 69 kDa 2'5' oligoadenylate synthetase; X02530, gamma-interferon inducible early response gene; L05072 Interferon regulatory factor 1 (IRF-1); X15949, Interferon regulatory factor 2 (IRF-2); X67325, Interferon-alpha inducible gene, p27 gene; H05300, Interferon-induced guanylate-binding protein 1; M55542, guanylate binding protein isoform II; D31887, KIAA0062 (cig 19); X88220, interferon inducible gene staf50; X02492, interferon-induced protein 6-16; R34698, interferon-inducible protein 9-27; M13755, interferon-induced 17 kDa/15 kDa protein; M28622, interferon beta; X17668, indoleamine 2,3-dioxygenase; M33882, MxA; M30818, MxB; X56841, HLA-E gene; T50250, est: homo to U51904, mouse IFN α-treated mRNA; M60618, nuclear autoantigen Sp100; M73778, PML-1; R39857, est = X97630 – serine/threonine protein kinase EMK; H02889, est = Y11366 IMPA gene; U25994, cell death protein (RIP protein kinase); D21209, protein tyrosine phosphatase (PTP-BAS type 1); X77278, HYL tyrosine kinase; R60908, est = X74764 – receptor protein tyrosine kinase; H65441, est = U78027, L35265 – Bruton's tyrosine kinase; and X16416, proto-oncogene tyrosine-protein kinase (abl), ~~wherein the first human cell sample comprises cells of a patient infected with HCMV~~, wherein the first human cell sample consists essentially of HCMV-infected cells of a patient infected with HCMV, wherein the expression levels of one or more genes of the set of genes correlates with stage of disease progression of the HCMV infection; and

determining a stage of disease progression based on the expression levels.

2. (Currently amended) A method of determining the extent of tissue damage caused by HCMV infection, comprising the step of:

determining expression levels in a first human cell sample of a set of genes comprising M24594, Interferon stimulated genes 54K; M87434, 71 kDa 2'5' oligoadenylate synthetase; X02875, (2'-5') oligo A synthetase E (1.8 kb RNA); X02874, (2'-5') oligo A synthetase E (1.6 kb RNA); M87284, 69 kDa 2'5' oligoadenylate synthetase; X02530, gamma-interferon inducible early response gene; L05072 Interferon regulatory factor 1 (IRF-1); X15949, Interferon regulatory factor 2 (IRF-2); X67325, Interferon-alpha inducible gene, p27 gene; H05300, Interferon-induced guanylate-binding protein 1; M55542, guanylate binding protein isoform II; D31887, KIAA0062 (cig 19); X88220, interferon inducible gene staf50; X02492, interferon-induced protein 6-16; R34698, interferon-inducible protein 9-27; M13755, interferon-induced 17 kDa/15 kDa protein; M28622, interferon beta; X17668, indoleamine 2,3-dioxygenase; M33882, MxA; M30818, MxB; X56841, HLA-E gene; T50250, est: homo to U51904, mouse IFN α-treated mRNA; M60618, nuclear autoantigen Sp100; M73778, PML-1; R39857, est = X97630 – serine/threonine protein kinase EMK; H02889, est = Y11366 IMPA gene; U25994, cell death protein (RIP protein kinase); D21209, protein tyrosine phosphatase (PTP-BAS type 1); X77278, HYL tyrosine kinase; R60908, est = X74764 – receptor protein tyrosine kinase; H65441, est = U78027, L35265 – Bruton's tyrosine kinase; and X16416, proto-oncogene tyrosine-protein kinase (abl),), ~~wherein the first human cell sample comprises cells of a patient infected with HCMV,~~ wherein the first human cell sample consists essentially of HCMV-infected cells of a patient infected with HCMV, wherein the expression levels of one or more genes in the set correlates with extent of tissue damage caused by the HCMV infection; and

determining the extent of tissue damage based on the expression levels.

3. (Currently amended) A method for screening to identify candidate drugs for preventing disease symptoms caused by HCMV, comprising the steps of:

contacting human cells with HCMV and a test agent;

determining expression levels of a set of genes comprising M24594, Interferon stimulated genes 54K; M87434, 71 kDa 2'5' oligoadenylate synthetase; X02875, (2'-5') oligo A synthetase E (1.8 kb RNA); X02874, (2'-5') oligo A synthetase E (1.6 kb RNA); M87284, 69 kDa 2'5' oligoadenylate synthetase;

X02530, gamma-interferon inducible early response gene; L05072 Interferon regulatory factor 1 (IRF-1); X15949, Interferon regulatory factor 2 (IRF-2); X67325, Interferon-alpha inducible gene, p27 gene; H05300, Interferon-induced guanylate-binding protein 1; M55542, guanylate binding protein isoform II; D31887, KIAA0062 (cig 19); X88220, interferon inducible gene staf50; X02492, interferon-induced protein 6-16; R34698, interferon-inducible protein 9-27; M13755, interferon-induced 17 kDa/15 kDa protein; M28622, interferon beta; X17668, indoleamine 2,3-dioxygenase; M33882, MxA; M30818, MxB; X56841, HLA-E gene; T50250, est: homo to U51904, mouse IFN α-treated mRNA; M60618, nuclear autoantigen Sp100; M73778, PML-1; R39857, est = X97630 – serine/threonine protein kinase EMK; H02889, est = Y11366 IMPA gene; U25994, cell death protein (RIP protein kinase); D21209, protein tyrosine phosphatase (PTP-BAS type 1); X77278, HYL tyrosine kinase; R60908, est = X74764 – receptor protein tyrosine kinase; H65441, est = U78027, L35265 – Bruton's tyrosine kinase; and X16416, proto-oncogene tyrosine-protein kinase (abl);

identifying a test agent as a candidate drug if the test agent causes the human cells to express one or more genes of the set of genes at a level at which the human cells express the one or more genes in the absence of HCMV.

4. (Cancelled)

5. (Currently amended) The method of claim 1, 2, or 3 wherein one or more genes of the set of genes are induced or repressed to a level which is at least two-fold different than the level of expression in the absence of HCMV.

6. (Currently amended) The method of claim 1, 2, or 3 wherein one or more genes of the set of genes are induced or repressed to a level which is at least four-fold different than the level of expression in the absence of HCMV.

7. (Currently amended) The method of claim 1, 2, or 3 wherein one or more genes of the set of genes are induced or repressed to a level which is at least eight-fold different than the level of expression in the absence of HCMV.

8. (Currently amended) The method of claim 1, 2, or 3 wherein one or more genes of the set of genes are induced or repressed to a level which is at least ten-fold different than the level of expression in the absence of HCMV.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,024	09/12/2001	Hua Zhu	03848.00096	1919

28315 7590 01/15/2004

BANNER & WITCOFF LTD.,
ATTORNEYS FOR AFFYMETRIX
1001 G STREET , N.W.
ELEVENTH FLOOR
WASHINGTON, DC 20001-4597

EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/950,024	ZHU ET AL.	
Examiner	**Art Unit**	
Young J. Kim	1637	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☒ Claim(s) *4,11 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Compliance Notice.*

PTO-1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTY. DOCKET NO. 03848.00096	SERIAL NUMBER TBA/Cont. 09/377,907
	APPLICANT Hau Zhu et al.	
	FILING DATE September 12, 2001	GROUP ART UNIT 1631

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
	5,561,071	10/1/1996	Hollenberg et al.			
	5,733,729	03/31/1998	Lipshutz et al.			
	5,795,716	08/18/98	Chee et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES/NO	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Shibutani et al. "Pertussis Toxin-sensitive G Proteins as Mediators of the Signal Transduction Pathways Activated by Cytomegalovirus Infection of Smooth Muscle Cells" The Journal of Clinical Investigation, Volume 100, Number 8, October 1997 pages 2054-2061
	Zhu et al. "Cellular gene expression altered by human cytomegalovirus: Global monitoring with oligonucleotide arrays" Proc. Natl. Acad. Sci. USA Vol. 95 pages 14470-14475, November 1998
	Geist and Dai "Cytomegalovirus Modulates Interleukin-6 Gene Expression" Transplantation, Vol. 62, No. 5, September 1996, pages 653-658
	Zhou et al. "Human Cytomegalovirus Increases Modified Low Density Lipoprotein Uptake and Scavenger Receptor mRNA Expression in Vascular Smooth Muscle Cells" The Journal of Clinical Investigation, Vol. 98, No. 9, November 1996, pages 2129-2138
	J. Zhu "Ultraviolet B irradiation and cytomegalovirus infection synergize to induce the cell surface expression of 52-kD/Ro antigen" Clin Exp. Immunol. 1996: 103:47-53
	Boldogh et al. "Novel Activation of γ-Interferon in Nonimmune Cells during Human Cytomegalovirus Replication" Proceedings of the Society for Experimental Biology and Medicine, Vol. 215, No. 1, May 1997
	Lois J. Geist et al. "The Immediate Early Genes of Human Cytomegalovirus Upregulate Tumor Necrosis Factor-α Gene Expression" J. Clin. Invest. Vol. 93, February 1994, pages 474-478
	Colberg-Poley and Santomenna "Selective Induction of Chromosomal Gene Expression by Human Cytomegalovirus" Virology, 1988, Vol. 166, pages 217-228
	Zhu et al. "Use of Differential Display and DNA Array Technology to Assess the Effect of Human Cytomegalovirus Infection on Signal Transeduction pathways. FASEB Journal, April 1998, Vol. 12, No. 8, page A1308

EXAMINER	DATE CONSIDERED 1-7-06

EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.